

CLAIM AMENDMENTS

Please amend claims 1, 5, 9-14, 17, 21, 25-28, 31, 33, 37, 41-46, 49, 53, 57-60, 63, 84 as follows:

1. (Currently amended) A method for determining the fertility status of a current ovulation cycle of a female human, comprising the steps of:
____(a) monitoring variation in tear concentration of at least one hormone of relevance to female fertility; and
____(b) evaluating the correspondence of the variation in tear concentration of said hormone to onset of the transition phase, fertile phase, ovulation, or infertile phase of a menstrual cycle in said female human, wherein the step of monitoring is performed by periodically collecting a tear fluid from the female human by the use of a tear-collecting device selected from the group consisting of a glass capillary tube, a hydrogel strip, and a contact lens and then determining the tear concentration of said hormone in the tear fluid.
2. (withdrawn) The method of claim 1, wherein the tear fluid is collected by the use of a tear-collecting device selected from the group consisting of a glass capillary tube and a hydrogel strip.
3. (withdrawn) The method of claim 2, wherein said tear-collecting device is a hydrogel strip, wherein said strip has a first end and an opposite second end, wherein said strip is made of a hydrogel material in substantially dry state and is characterized by having a substantially uniform swelling along that hydrogel strip from the first end to the second end when fully wicked by a tear fluid and by having a correlation between the volume of tear uptake by that strip and the length of a tear-wicked end portion of that strip.
4. (withdrawn) The method of claim 2, wherein the tear fluid is collected daily upon waking or at approximately a fixed time in the morning.
5. (Currently amended) The method of claim 1, wherein the tear fluid is collected daily by (1) placing the contact lens in the eye of having the female human; (2) minimizing or eliminating biological concentration variability of said hormone in the tear fluid by wearing the a-contact lens on the an eye for at least 30 minutes; and (3) then by removing the contact lens from the eye.

6. (Original) The method of claim 5, wherein the tear fluid is collected daily at the end of each day, after wearing for more than 6 hour.
7. (Original) The method of claim 5, wherein said contact lens is a soft contact lens, a hydrogel soft contact lens, or a daily disposable hydrogel soft contact lens.
8. (Original) The method of claim 5, wherein said contact lens is a contact lens capable of binding said hormone, wherein the contact lens includes: (1) surface charges present in a density sufficient to impart to the contact lens an increased adsorption of said hormone; (2) a coating comprising a receptor which binds specifically said hormone; (3) molecular imprints for said hormone; or (4) a core material that is prepared from a composition containing a receptor which binds specifically said hormone.
9. (Currently amended) The method of claim 54, wherein the first collecting of tear fluid in the current cycle is made at the cessation of menses.
10. (Currently amended) The method of claim 54, wherein the first collecting of tear fluid in the current cycle is made at least at 3 days following the onset of menses.
11. (Currently amended) The method of claim 54, wherein said hormone is estrogen, and wherein a significant increase in its tear concentration or a determined estrogen tear concentration being higher than a threshold value, following the cessation of menses, is indicative of the onset of the fertile period.
12. (Currently amended) The method of claim 54, wherein said hormone is LH, wherein detection of a LH surge or a determined LH tear concentration being higher than a threshold value, indicates that the female human will no longer be fertile four days hence (3 days after ovulation).
13. (Currently amended) The method of claim 54, wherein said hormone is progesterone, wherein the end of the fertile period can be predicted by detecting a significant increase in progesterone tear concentration or by detecting a progesterone tear concentration being higher than a threshold value following the cessation of menses.
14. (Currently amended) The method of claim 54, wherein at least two of estrogen, LH and progesterone are monitored to determine the status of a menstrual cycle of the female human.
15. (Original) The methd of claim 14, wherein estrogen and progesterone are monitored to determine the status of a menstrual cycle of the female human.

16. (Original) The method of claim 15, wherein the estrogen is estradiol, wherein a significant increase in the tear concentration ratio of estradiol to progesterone or a determined value of the tear concentration ratio of estradiol to progesterone being higher than a threshold value, following the cessation of menses, is indicative of the onset of the fertile period.
17. (Currently amended) A method for determining the fertility status of a current ovulation cycle of a female human, comprising a series of steps performed at least once per day for at least several days preceding and following ovulation, said steps comprising: (a) collecting a tear fluid from the female human by the use of a tear-collecting device selected from the group consisting of a glass capillary tube, a hydrogel strip, and a contact lens; (b) determining variation in tear concentration of at least one hormone of relevance to female fertility to establish variation in tear concentration of said hormone; and (c) evaluating the correspondence of the variation in tear concentration of said hormone to onset of the fertile phase, ovulation, or infertile phase of a menstrual cycle in said female human.
18. (withdrawn) The method of claim 17, wherein the tear fluid is collected by the use of a tear-collecting device selected from the group consisting of a glass capillary tube and a hydrogel strip.
19. (withdrawn) The method of claim 18, wherein the tear fluid is collected daily upon waking or at approximately a fixed time in the morning.
20. (withdrawn) The method of claim 18, wherein said tear-collecting device is a hydrogel strip, wherein said strip has a first end and an opposite second end, wherein said strip is made of a hydrogel material in substantially dry state and is characterized by having a substantially uniform swelling along that hydrogel strip from the first end to the second end when fully wicked by a tear fluid and by having a correlation between the volume of tear uptake by that strip and the length of a tear-wicked end portion of that strip.
21. (Currently amended) The method of claim 17, wherein the tear fluid is collected daily by (1) placing the contact lens in the eye of having the female human; (2) minimizing or eliminating biological concentration variability of said hormone in the tear fluid by wearing the a-contact lens on the an eye for at least 30 minutes; and (3) then by removing the contact lens from the eye.

22. (Original) The method of claim 21, wherein the tear fluid is collected daily at the end of each day, after wearing for more than 6 hour.
23. (Original) The method of claim 21, wherein said contact lens is a soft contact lens, a hydrogel soft contact lens, or a daily disposable hydrogel soft contact lens.
24. (Original) The method of claim 21, wherein said contact lens is a contact lens capable of binding said hormone, wherein the contact lens includes: (1) surface charges present in a density sufficient to impart to the contact lens an increased adsorption of said hormone; (2) a coating comprising a receptor which binds specifically said hormone; (3) molecular imprints for said hormone; or (4) a core material that is prepared from a composition containing a receptor which binds specifically said hormone.
25. (Currently amended) The method of claim ~~2147~~, wherein said hormone is estrogen, and wherein a significant increase in its tear concentration or a determined estrogen tear concentration being higher than a threshold value, following the cessation of menses, is indicative of the onset of the fertile period.
26. (Currently amended) The method of claim ~~2147~~, wherein said hormone is LH, wherein detection of a LH surge or a determined LH tear concentration being higher than a threshold value, indicates that the female human will no longer be fertile four days hence (3 days after ovulation).
27. (Currently amended) The method of claim ~~2147~~, wherein said hormone is progesterone, wherein the end of the fertile period can be predicted by detecting a significant increase in progesterone tear concentration or by detecting a progesterone tear concentration being higher than a threshold value following the cessation of menses.
28. (Currently amended) The method of claim ~~2147~~, wherein at least two of estrogen, LH and progesterone are monitored to determine the status of a menstrual cycle of the female human.
29. (Original) The method of claim 28, wherein estrogen and progesterone are monitored to determine the status of a menstrual cycle of the female human.
30. (Original) The method of claim 29, wherein the estrogen is estradiol, wherein a significant increase in the tear concentration ratio of estradiol to progesterone or a determined value of the tear concentration ratio of estradiol to progesterone being higher

than a threshold value, following the cessation of menses, is indicative of the onset of the fertile period.

31. (Currently amended) The method of claim ~~2147~~, further comprising conducting at least one test for the tear concentration of said hormone in the period from day 1 up to and including day 7 calculated from the onset of menses, to establish a base concentration value or signal for said hormone in the current cycle.
32. (Original) The method of claim 31, wherein the base concentration value is established from test(s) conducted on day 5 and/or day 6.
33. (Currently amended) A birth control method, comprising the steps of: (a) monitoring variation in tear concentration of at least one hormone of relevance to female fertility; (b) evaluating the correspondence of the variation in tear concentration of said hormone to onset of the fertile phase, ovulation, and/or terminal infertile period of a menstrual cycle in said female human; and (c) causing said female human to avoid exposure to fertilization beginning at least at the onset of the fertile phase and ending day "+2" relative to the day of actual ovulation, wherein the step of monitoring is performed by periodically collecting a tear fluid from the female human by the use of a tear-collecting device selected from the group consisting of a glass capillary tube, a hydrogel strip, and a contact lens and then determining the tear concentration of said hormone.
34. (withdrawn) The method of claim 33, wherein the tear fluid is collected by the use of a tear-collecting device selected from the group consisting of a glass capillary tube and a hydrogel strip.
35. (withdrawn) The method of claim 34, wherein the tear fluid is collected daily upon waking or at approximately a fixed time in the morning.
36. (withdrawn) The method of claim 34, wherein said tear-collecting device is a hydrogel strip, wherein said strip has a first end and an opposite second end, wherein said strip is made of a hydrogel material in substantially dry state and is characterized by having a substantially uniform swelling along that hydrogel strip from the first end to the second end when fully wicked by a tear fluid and by having a correlation between the volume of tear uptake by that strip and the length of a tear-wicked end portion of that strip.
37. (Currently amended) The method of claim 33, wherein the tear fluid is collected daily by (1) placing the contact lens in the eye of having the female human; (2) minimizing or eliminating biological concentration variability of said hormone in the tear fluid by

wearing the ~~a~~-contact lens on the ~~an~~ eye for at least 30 minutes; and (3) ~~then~~ by removing the contact lens from the eye.

38. (Original) The method of claim 37, wherein the tear fluid is collected daily at the end of each day, after wearing for more than 6 hour.
39. (Original) The method of claim 37, wherein said contact lens is a soft contact lens, a hydrogel soft contact lens, or a daily disposable hydrogel soft contact lens.
40. (Original) The method of claim 37, wherein said contact lens is a contact lens capable of binding said hormone, wherein the contact lens includes: (1) surface charges present in a density sufficient to impart to the contact lens an increased adsorption of said hormone; (2) a coating comprising a receptor which binds specifically said hormone; (3) molecular imprints for said hormone; or (4) a core material that is prepared from a composition containing a receptor which binds specifically said hormone.
41. (Currently amended) The method of claim ~~37~~33, wherein the first collecting of tear fluid in the current cycle is made at the cessation of menses.
42. (Currently amended) The method of claim ~~37~~33, wherein the first collecting of tear fluid in the current cycle is made at least at 3 days following the onset of menses.
43. (Currently amended) The method of claim ~~37~~33, wherein said hormone is estrogen, and wherein a significant increase in its tear concentration or a determined estrogen tear concentration being higher than a threshold value, following the cessation of menses, is indicative of the onset of the fertile period.
44. (Currently amended) The method of claim ~~37~~33, wherein said hormone is LH, wherein detection of a LH surge or a determined LH tear concentration being higher than a threshold value, indicates that the female human will no longer be fertile four days hence (3 days after ovulation).
45. (Currently amended) The method of claim ~~37~~33, wherein said hormone is progesterone, wherein the end of the fertile period can be predicted by detecting a significant increase in progesterone tear concentration or by detecting a progesterone tear concentration being higher than a threshold value following the cessation of menses.
46. (Currently amended) The method of claim ~~37~~33, wherein at least two of estrogen, LH and progesterone are monitored to determine the status of a menstrual cycle of the female human.

47. (Original) The method of claim 46, wherein estrogen and progesterone are monitored to determine the status of a menstrual cycle of the female human.
48. (Original) The method of claim 47, wherein the estrogen is estradiol, wherein a significant increase in the tear concentration ratio of estradiol to progesterone or a determined value of the tear concentration ratio of estradiol to progesterone being higher than a threshold value, following the cessation of menses, is indicative of the onset of the fertile period.
49. (Currently amended) A birth control method, comprising a series of steps performed at least once per day for at least several days preceding and following ovulation, said steps comprising: (a) collecting a tear fluid from the female human by the use of a tear-collecting device selected from the group consisting of a glass capillary tube, a hydrogel strip, and a contact lens; (b) determining variation in tear concentration of at least one hormone of relevance to female fertility to establish variation in tear concentration of said hormone; (c) evaluating the correspondence of the variation in tear concentration of said hormone to onset of the fertile phase, ovulation, and/or terminal infertile period of a menstrual cycle in said female human; and (c) causing said female human to avoid exposure to fertilization beginning at least at the onset of the fertile phase and ending day "+2" relative to the day of actual ovulation.
50. (withdrawn) The method of claim 49, wherein the tear fluid is collected by the use of a tear-collecting device selected from the group consisting of a glass capillary tube and a hydrogel strip.
51. (withdrawn) The method of claim 50, wherein the tear fluid is collected daily upon waking or at approximately a fixed time in the morning.
52. (withdrawn) The method of claim 50, wherein said tear-collecting device is a hydrogel strip, wherein said strip has a first end and an opposite second end, wherein said strip is made of a hydrogel material in substantially dry state and is characterized by having a substantially uniform swelling along that hydrogel strip from the first end to the second end when fully wicked by a tear fluid and by having a correlation between the volume of tear uptake by that strip and the length of a tear-wicked end portion of that strip.
53. (Currently amended) The method of claim 49, wherein the tear fluid is collected daily by (1) placing the contact lens in the eye of having the female human; (2) minimizing or eliminating biological concentration variability of said hormone in the tear fluid by

wearing the ~~a~~ contact lens on the ~~an~~ eye for at least 30 minutes; and (3) ~~then~~ by removing the contact lens from the eye.

54. (Original) The method of claim 53, wherein the tear fluid is collected daily at the end of each day, after wearing for more than 6 hour.
55. (Original) The method of claim 53, wherein said contact lens is a soft contact lens, a hydrogel soft contact lens, or a daily disposable hydrogel soft contact lens.
56. (Original) The method of claim 53, wherein said contact lens is a contact lens capable of binding said hormone, wherein the contact lens includes: (1) surface charges present in a density sufficient to impart to the contact lens an increased adsorption of said hormone; (2) a coating comprising a receptor which binds specifically said hormone; (3) molecular imprints for said hormone; or (4) a core material that is prepared from a composition containing a receptor which binds specifically said hormone.
57. (Currently amended) The method of claim 5349, wherein said hormone is estrogen, and wherein a significant increase in its tear concentration or a determined estrogen tear concentration being higher than a threshold value, following the cessation of menses, is indicative of the onset of the fertile period.
58. (Currently amended) The method of claim 5349, wherein said hormone is LH, wherein detection of a LH surge or a determined LH tear concentration being higher than a threshold value, indicates that the female human will no longer be fertile four days hence (3 days after ovulation).
59. (Currently amended) The method of claim 5349, wherein said hormone is progesterone, wherein the end of the fertile period can be predicted by detecting a significant increase in progesterone tear concentration or by detecting a progesterone tear concentration being higher than a threshold value following the cessation of menses.
60. (Currently amended) The method of claim 5349, wherein at least two of estrogen, LH and progesterone are monitored to determine the status of a menstrual cycle of the female human.
61. (Original) The method of claim 60, wherein estrogen and progesterone are monitored to determine the status of a menstrual cycle of the female human.
62. (Original) The method of claim 61, wherein the estrogen is estradiol, wherein a significant increase in the tear concentration ratio of estradiol to progesterone or a

determined value of the tear concentration ratio of estradiol to progesterone being higher than a threshold value, following the cessation of menses, is indicative of the onset of the fertile period.

63. (Currently amended) The method of claim ~~5349~~, further comprising conducting at least one test for the tear concentration of said hormone in the period from day 1 up to and including day 7 calculated from the onset of menses, to establish a base concentration value or signal for said hormone in the current cycle.
64. (Original) The method of claim 63, wherein the base concentration value is established from test(s) conducted on day 5 and/or day 6.
- 65-83. (Canceled)
84. (Currently amended) A method for determining the fertility status of a current ovulation cycle of a female non-human mammal, comprising the steps of: (a) monitoring variation in tear concentration of at least one hormone of relevance to female fertility; and (b) evaluating the correspondence of the variation in tear concentration of said hormone to onset of the transition phase, fertile phase, ovulation, or infertile phase of a menstrual cycle in said female nonhuman mammal, wherein the step of monitoring is performed by periodically collecting a tear fluid from the female nonhuman mammal by the use of a tear-collecting device selected from the group consisting of a glass capillary tube, a hydrogel strip, and a contact lens and then determining the tear concentration of said hormone.
85. (withdrawn) The method of claim 84, wherein the tear fluid is collected by the use of a tear-collecting device selected from the group consisting of a glass capillary tube and a hydrogel strip.
86. (Original) The method of claim 84, wherein said hormone is estrogen, and wherein a significant increase in its tear concentration or a determined estrogen tear concentration being higher than a threshold value, following the cessation of menses, is indicative of the onset of the fertile period.
87. (Original) The method of claim 84, wherein said hormone is LH, wherein detection of a LH surge or a determined LH tear concentration being higher than a threshold value, indicates that the female nonhuman mammal will no longer be fertile four days hence (3 days after ovulation).
88. (Original) The method of claim 84, wherein said hormone is progesterone, wherein the end of the fertile period can be predicted by detecting a significant increase in

progesterone tear concentration or by detecting a progesterone tear concentration being higher than a threshold value following the cessation of menses.

89. (Original) The method of claim 84, wherein at least two of estrogen, LH and progesterone are monitored to determine the status of a menstrual cycle of the female nonhuman mammal.
90. (Original) The method of claim 89, wherein estrogen and progesterone are monitored to determine the status of a menstrual cycle of the female nonhuman mammal.
91. (Original) The method of claim 90, wherein the estrogen is estradiol, wherein a significant increase in the tear concentration ratio of estradiol to progesterone or a determined value of the tear concentration ratio of estradiol to progesterone being higher than a threshold value, following the cessation of menses, is indicative of the onset of the fertile period.